DECIMOCUARTA: ARBITRAJE

Cualquier diferencia que surja en la interpretación de este contrato, será resuelta de común acuerdo por un representante de cada una de las partes. En el supuesto de que éstas no se pongan de acuerdo, las partes se obligan a someterse a la decisión de un árbitro, que será designado de común acuerdo por ambas partes. En caso de que no puedan ponerse de acuerdo sobre el árbitro, éste, a petición de una de las partes, será nombrado por la Cámara Oficial de Industria y Comercio de Madrid. Las partes se comprometen a cumplir todas y cada una de las formalidades exigidas por la ley española.

DECIMOQUINTA: DISPOSICIONES FINALES

15.1 Cuando las disposiciones de este contrato fuesen o se volviesen insuficientes, o cuando se presente alguna duda sobre el mismo, la validez de las demás disposiciones no se alterarán.

15.2 Cuando se cambien o se completen disposiciones individuales de este contrato se adjuntarán al mismo por escrito en forma de acuerdo adicional.

En este contrato se han adjuntado los siguientes anexos:

- Anexo 1: Productos contractuales.
- Anexo 2: Normas para la Fabricación y Control de Calidad. Acondicionamiento de salas de fabricación, encapsulado y relacionados.
- Anexo 3: Maquinaria, materiales, instalaciones y elementos de fabricación.
- Anexo A: Precio. Aportación NBF licencias y otros.
- Anexo B: Firma de los operarios como compromiso de secreto.

Los convenios adicionales por escrito (y anexos) se consideran como parte integrante de este contrato y deberán ser aprobados y firmados por los representantes autorizados de las partes contratantes.

En prueba de conformidad con lo anteriormente expuesto y pactado ambas partes forman el presente contrato por duplicado y con la fecha del encabezamiento.

Madrid, a

D. Angel Pérez de Ayala
LABORATORIOS BELMAC,S.A

D. Patrice Debregeas
ETHYPHARM,S.A.

ANEXO 1

PRODUCTOS CONTRACTUALES

Los productos objeto de este contrato, son los siguientes:

1.- Omeprazol 20 mg.

2.- Fenofibrato 250 mg.

3.- Acido Acetil Salicílico 300mg.

ANEXO 2

2.1 Normas para la fabricación y Control de Calidad, según dossier adjunto.

2.2 Proyecto de Acondicionamiento de salas de fabricación, pesadas, preparación de soluciones, almacenaje, lavado y encapsulado. (Ya entregado para la solicitud de la Inspección de Sanidad

2.3 Normas de Buena fabricación y Control y sus validaciones.

ANEXO 3

Los elementos para las fabricaciones de Ethypharm que además son propiedad de ésta, son los siguientes:

- 1 AUTOMATA SIEMENS OP 393-II
- 1 CUADRO PROGRAMADOR DE SALAS
- 3 AUTOMATAS DE SALAS DEPENDIENTES DEL GENERAL
- 6 PAILAS REF.150 RE + 6 INSUFLADORES DE AIRE CALIENTE REF.3R
- 2 EQUIPOS DE PULVERIZACION (4 PISTOLA AA3000 + 8 PIES PARA PISTOLA + 2 BOMBAS A PRESION + 4 PEDALES + BOQUILLAS)
- 3 TAMIZ VIBRATORIO WESTON REF.503-3 + 9 MALLAS + SOPORTE MALLAS
- 8 BIDONES DE PLASTICO CON ASAS Y TAPADERAS
- 1 MICRONIZADOR FORPLEX 00 + MALLA 0,1 mm
- 1 MINITERMOMETRO ELECTRONICO TIPO ABM11.03+SONDA REF.A2864441
- 4 SOPORTES PARA PALAS CORTADORAS DE FLUJO
- 1 DISOLUTEST
- 1 TERMINAL DE PESADA METTLER MULTIRANGE ID5
- 1 IMPRESORA METTLER MULTIRANGE GD46
- 1 BALANZA SUELO EMPOTRABLE KCS 300
- 1 BALANZA DE PRECISION METTLER
- 1 MAQUINA ENCAPSULADORA MOD.MG36
- 1 SELECCIONADOR DE CAPSULAS MG2
- 1 JUEGO MALLAS TAMIZ
- 1 ARCHIVADOR
- 1 TABLA DE CALIBRAR T1
- 1 ORDENADOR EPSON PX16
- 1 BALANZA DE PRECISION METLER PM100

Pequeño material:

- 1 ESCALERA
- 1 ARCHIVADOR
- 2 CEPILLOS especiales
- 3 PAPELERAS
- 4 PALAS DE MANGO CORTO INOX
- 2 CUBO INOX 10l
- 2 FRASCAS INOX
- 4 ESPATULA INOX
- 1 CUCHILLO
- 1 RELOJ DE PARED
- Esponja PVA, Pinza sujeta esponja, Palo telescópico

Esta maquinaria y materiales serán alquilados por ETHYPHARM a BELMAC, según lo establecido en la estipulación TERCERA (3.5).

-Salas de fabricacion y su acondicionamiento:

El acondicionamiento de las salas de fabricación y el P.M.F. son propiedad de **ETHYPHARM.**

ETHYPHARM ha asistido tecnicamente a **BELMAC** para obtener que sus instalaciones cumplan con las normas GMP (Good Manufacturing Practices) comunitarias. Los gastos debidos a esta asistencia técnica serán a cargo de **BELMAC.**

Los otros elementos para el valor y control de los productos de **ETHYPHARM**, que son propiedad de **BELMAC**, son los siguientes:

- Material necesario para control:
  - HPLC
  - PEQUEÑO MATERIAL

Estos aparatos están incluidos en el cálculo del precio del control analítico que **BELMAC** cobrará a **ETHYPHARM.**

ESPACIO DE ALMACENAMIENTO

Descripción del almacenamiento mínimo según la estipulación QUINTA (5.2):

ANEXO A

Precio

El precio que aplicará **BELMAC** a las fabricaciones y control de los productos de **ETHYPHARM** será el que resulte de los costos reales de cada lote de fabricación tomando como referencia de tiempos los estandar de fabricación de **ETHYPHARM** según los escandallos correspondientes a cada uno de los productos que se adjuntan a este contrato. **BELMAC** cargará únicamente un margen correspondiente al beneficio industrial del 15%.

Los excipientes empleados en dichas fabricaciones, serán cargados a los mismos precios de suministro establecidos por los proveedores designados por **ETHYPHARM**.

ETHYPHARM abonará sus facturas con un plazo de 60 días a partir de la entrega al cliente.

Aportación de Normas de Buena Fabricación (NBF). Licencias.

ETHYPHARM FRANCIA y en su representación su Presidente Director General D.Patrice Debregeas ofrece un derecho preferencial a **BELMAC** para obtener la licencia de los productos, que se discutirán fuera de éste contrato, inicialmente Ibuprofeno y Dinitrato de Isosorbida.

ANEXO B

Firma de los operarios y técnicos

Los abajo firmantes se comprometen a respetar las condiciones descritas en la Estipulación **DECIMA** del presente contrato (OBLIGACION DE GUARDAR SECRETO).

Fdo. D. José Luis Monterde
(farmacéutico)

Fdo. D. Juan Carlos Asensio
(farmacéutico)

Fdo. D. Francisco Poderos
(perito Industrial)

Fdo. D. José García Trigo

Fdo. D. Mateo Gasca
(farmacéutico)

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

December 1, 1993

Manufacturing Contract

[By and between]

ETHYPHARM, S. A. (hereinafter **ETHYPHARM**) with corporate headquarters at Marqués de la Ensenada, 16 28004 Madrid, represented by its duly empowered Chairman Mr. Patrice Debregeas,

And

The **Laboratórios BELMAC, S. A.** company (hereinafter **BELMAC**) with corporate headquarters at Paseo de la Castellana 149, Piso Dcha. Madrid 28046,

Represented by its duly empowered Chief Executive Officer Angel Pérez de Ayala, who

HEREBY DECLARE

First, that **ETHYPHARM** and **BELMAC** are interested in the manufacture and capsule filling by **BELMAC** of **ETHYPHARM**'s products as set forth under Appendix 1.
Second, that for said purpose they have decided that the collaboration between the parties shall be governed by the following:

COVENANTS

One – ETHYPHARM guarantees to **BELMARC** the task of an annual minimal manufacture of 60 Lots, of any of the products set forth in Appendix 1, that shall be broadened to include new products by common agreement of the parties. With regard to the quantity that exceeds what has been specified, **ETHYPHARM** offers **BELMAC** a preferential right to manufacture the products under this contract up to the manufacturing capacity of the latter in Spain.

Two – BELMAC warrants to **ETHYFARM** that it will undertake strict compliance with Best Manufacturing Practices for all products under this contract and compliance by its facilities [or installations] of the aforementioned standards and basic WHO standards on the manufacture of medicines, the latter being answerable to the Administrative Health Authorities and all others for any non-compliance.

Three – Manufacture in Capsule Form and Quality Control

3.1 – **BELMAC** shall manufacture on an exclusive basis for Spain the products under this contract set forth under Appendix 1 according to **ETHYPHARM**'s standards and specifications for the manufacture and quality control of the products under the contract (see Appendix 2.1). Changes to this specifications require the written approval of **ETHYPHARM** and for any non-compliance therewith, **BELMAC** shall be accountable to the administrative, health and other authorities.

However, **ETHYPHARM** shall assume responsibility for any problem that clearly arises from the standards it has established.

3.2 – **ETHYPHARM** or its customers, shall supply to **BELMAC** the **active principles** stated in conformance with the specifications given by **ETHYPHARM** to its customers.

BELMAC shall proceed to make qualitative and quantitative identification of said active principles.

In the event that the result of an identification analysis undertaken by **BELMAC** is found to be non-conforming (said analysis should be carried out in the five (5) first days after receipt of the active principles). **BELMAC** shall so inform **ETHYPHARM** in writing immediately, and the latter shall take the proper measures to have its customers provide a substitute or cause to be substituted said non-conforming active principles.

3.3 – **ETHYPHARM** shall determine the specifications of the excipients required for manufacturing the products and **BELMAC** agrees to use only excipients that conform to said specifications.

3.4 – ETHYFARM is placing at **BELMAC**'s disposal the know-how and machines required for manufacturing and capsule filling of the contractual products according to **ETHYPHARM**'s standards. All the machinery, materials or facilities (installations) required for the manufacturing and the conditioning of the rooms in which said manufacturing must occur are described under Appendix 3 and are the sole property of **ETHYPHARM** (with the exception of those that are recognized as belonging to **BELMAC**).

3.5 **BELMAC** agrees to state [or record] in any event and to all third parties that said machinery and facilities are not its property but the property of **ETHYPHARM**. With regard to facilities [or installations] that cannot be physically removed and thus would remain in the building, **BELMAC** shall be obligated to provide **ETHYPHARM** an equivalent quantity [sic] at the purchase price plus customs' levies and transportation costs in the event of importation, minus amortization [expense], which **ETHYPHARM** would have made of said facilities or at least the amortization [expense] that, given the nature of the installations, that may be legally demanded of it. This same system shall prevail in the event of contract termination arising from normal causes of expiration pursuant to any of the agreed contractual terms (duration). Also, it shall prevail when contract termination arises due to unilateral rescission by **BELMAC** or by rescission of the contract by **ETHYPHARM** on the basis of non-compliance by **BELMAC** of its contractual obligations and the same system shall not apply [sic], and the installations that may not be removed will be the property of **BELMAC** and at its free disposition, in the event the rescission occurs due to non-compliance with contractual obligations by **ETHYPHARM** or by rescission freely undertaken by the latter's desire and that is not based on contractual non-compliance by **BELMAC**.

3.6 The parties herewith agree that **BELMAC** shall exchange at no charge any manufacturing lot considered to be definitively out of conformance with the specifications given by **ETHYPHARM** and accepted by **BELMAC**. In the event that any lot is defective due to incorrect specifications given by **ETHYPHARM**, the latter shall in all events be obligated to pay **BELMAC** for the same manufacturing price it would have paid had the lot not been defective.

3.7 The finished products manufactured by **BELMAC** shall, should this apply, have on the packaging or label the marks and indications that **ETHYPHARM**'s customer proposes and the texts in conformance with legal requirements, provided by the customer on the materials relating thereto.

Four – Technical and Workforce Assistance

[...]

Five – Supply of Raw Materials

[...]

Six – Logistics

[…]

Seven – Distribution

[…]

Eight – Production Costs

[…]

Nine – Commercial Rights

[…]

Ten – Secrecy Obligation

Eleven – Assignment of Rights

11.1 The parties herewith shall not assign the rights hereunder without the prior consent in writing by the other party.

11.2 **BELMAC** shall immediately communicate to ETHYRAM in writing any basic changes (greater than or equal to 25%) that might occur in the shareholders of its capital stock.

However, **ETHYPHARM** is authorized to assign its rights and obligations hereunder to companies and institutions in which it owns more than a 50% interest of capital stock or assets.

Twelve – Contract Term

12.1 This contract shall have a five year term that may be renewed for periods of two years, except that in the nine months prior to its first expiration date or any of the successive renewals, one of the contracting parties notifies, before a notary, the other of its intention not to renew.

12.2 In the event of non-compliance with contractual obligations by one of the parties, the other party shall be entitled to terminate said contract if, after it has so communicated in writing, within a period of two (2) months, proper measures have not be taken to remedy the breach, assuming said breach may be remedied. In the event the contract is not terminated within the two month period after the previous term, the right to terminate on the basis of this specific basis shall be extinguished.

12.3 In the event there were a modification [of ownership] due to a person or company becoming a shareholder in the group of companies of the current shareholders of **BELMAC**, **ETHYPHARM** shall be authorized to rescind the contract within a period of six (6) months.

12.4 When the contracts ends, all manufacturing documents, know-how and quality control document shall be remitted to **ETHYPHARM**.

Thirteen – Non-competition

BELMAC agrees that during the term of validity of this contract and for five years thereafter, to neither manufacture micro-granules, not even for itself, nor cause products, as set forth under Appendix 1, similar to the ones under this contract to be manufactured that might compete with the **ETHYPHARM** products without its prior authorization.

Fourteen – Arbitration

Fifteen – Final Provisions

[...]

Angel Pérez de Ayala
LABORATORIOS BELMAC, S. A.

Patrice Debregeas
ETHYPHARM, S. A.

Appendix 1

Products under this contract

The products under this contract are:

1- 20 mg. Omeprazol

2 – 250 mg. Fenofibrate

3 - 300 mg. Salicylic acetic acid

Appendix 2

2.1 Standards for manufacturing and Quality Control according to attached file.

2.2 Plan for outfitting the manufacturing, weighing, solution preparation, storing, washing and capsule filling. (Has already been handed in for the request from the health inspection) [sic]

2.3 Best Manufacturing And Control Standards and Validation

J.Y B. CREMADES Y ASOCIADOS
. ABOGADOS
GOYA, 18 - 28001 MADRID
FAX (34) 578 97 94
TEL. (34) 431 83 84

61, AV. GEORGES MANDEL
75116 PARIS
TEL. (331) 45 53 53 50
FAX (331) 45 63 65 40

AV. LOUISE, 391
1050 BRUXELLES
TEL. (322) 648 98 40
FAX (322) 647 03 31

TELEFAX NUMERO 30.412 /95

A: ADOLFO DE BASILIO
ETHYPHARM
(319 91 59, MADRID)

DE: JAVIER SANTOS
(576 97 94, MADRID)

FECHA: 15 DE MARZO DE 1.995

REF: 7.197/XXIII

PAGINAS: 1 + 10

****
POR FAVOR LLAME POR TELEFONO 431 83 54 CASO DE DETECTAR CUALQUIER PROBLEMA EN LA TRANSMISION DEL FAX.
****

Estimado Adolfo:

Como acordamos, adjunto te remito borradores de contratos a suscribir entre Belmac y Ethypharm.

Quedo a la espera de tus comentarios.

Un saludo,

Javier Santos

JS/mb

archivo:
Contrato Belmac

EXHIBIT
Dubois
4
ms 7.12.06

EXHIBIT
Debregas
9
AD 7.12.06

EP 009082

A-175

DRAFT 14 MARCH 1995

MEMORANDUM OF UNDERSTANDING

In Madrid, on __ March 1995

GATHER TOGETHER

- Mr. James R. Murphy, on behalf and in representation of LABORATORIOS BELMAC, S.A. (hereinafter referred to as "BELMAC"), with corporate domicile at Paseo de la Castellana, 149, 28046 Madrid; he uses the faculties and powers granted to him as Executive Director of BELMAC.

- Mr. Patrica Debregeas, on behalf and in representation of ETHYPHARM, S.A. (hereinafter referred to as "ETHYPHARM"), with corporate domicile at Marqués de la Ensenada, 15, 28004 Madrid and on behalf and in representation of ETHYPHARM, S.A. (hereinafter referred to as "ETHYPHARM FRANCE"), with corporate domicile at 21 Rue Saint Matthieu, Houdan 78550, France. He uses faculties and powers granted to him as Chairman of both ETHYPHARM and ETHYPHARM FRANCE.

THEY STATE

I. That BELMAC is a company with an active presence in the pharmaceutical industry, and owns a factory in Spain authorised to be used as a pharmaceutical laboratory.

II. That ETHYPHARM is a company with an active presence in the pharmaceutical industry and possesses wide experience as a drug delivery company.

III. That BELMAC and ETHYPHARM are interested in collaborating together in order to combine their efforts in areas of common interest to both parties.

THEY AGREE

I. BELMAC and ETHYPHARM will endeavour to combine their best efforts in areas such as the improvement of the development of new pharmaceutical products, research to develop new extended release and dosage forms of well-established products, exploring potential and new markets, use and benefit from each party's licenses and knowledge, etc.

II. Each specific project of collaboration will be discussed by BELMAC and ETHYPHARM in good faith and will be the object of a separate and individual agreement.

III. This Memorandum of Understanding is not intended to be a binding commitment for the parties but simply each party's compromise to negotiate in good faith. Said compromise will be in force unless one of the parties rescinds the collaboration by giving a six-months advance notice to the other party.

IV. ETHYPHARM FRANCE will provide all the necessary support and knowledge to ETHYPHARM so that the latter can meet its obligations as set out in any individual agreement which may be accorded between BELMAC and ETHYPHARM.

V. The information exchanged by the parties pursuant to this Memorandum of Understanding will be kept confidential. In the event that the parties agree to discontinue negotiations, all confidential data will be returned to the other party within thirty days after receiving the notice to rescind, unless otherwise stated in any individual agreement.

VI. The notifications or communications derived from this Memorandum of Understanding should be sent to the following persons at the following addresses and fax numbers:

a) For BELMAC:
address:
attention:
fax number:

b) For ETHYPHARM:
address:
attention:
fax number:

c) For ETHYPHARM FRANCE:
address:
attention:
fax number:

In witness thereof, the parties sign this document at the place and on the date mentioned above.

BELMAC	ETHYPHARM	ETHYPHARM FRANCE
Name:	Name:	Name:
Title:	Title:	Title:

DRAFT 14 MARCH 1995

MANUFACTURING AGREEMENT

In Madrid, on __ March 1995

GATHER TOGETHER

- Mr. James R. Murphy, on behalf and in representation of LABORATORIOS BELMAC, S.A. (hereinafter referred to as "BELMAC"), with corporate domicile at Paseo de la Castellana, 149, 28046 Madrid; he uses the faculties and powers granted to him as Executive Director of BELMAC.

- Mr. Patrice Debregeas, on behalf and in representation of ETHYPHARM, S.A. (hereinafter referred to as "ETHYPHARM"), with corporate domicile at Marqués de la Ensenada, 16, 28004 Madrid and on behalf and in representation of ETHYPHARM, S.A. (hereinafter referred to as "ETHYPHARM FRANCE"), with corporate domicile at 21 Rue Saint Matthieu, Houdan 78550, France. He uses faculties and powers granted to him as Chairman of both ETHYPHARM and ETHYPHARM FRANCE.

THEY STATE

I. That ETHYPHARM is interested in contracting BELMAC for the manufacture, encapsulation and or fitting out (hereinafter to be referred to as "the manufacture") of certain products as described in Annex 1 (hereinafter referred to as "the products") for the purpose of their delivery to third parties (hereinafter referred to as "the client" or "the clients").

II. That BELMAC is interested in the manufacture of the products for their eventual delivery to the clients.

The parties, having regard for that stated above, with the express intention of reflecting their respective obligations in a written and binding agreement, and mutually acknowledging each party's capacity thereon, have decided to subscribe to the present agreement (hereinafter, the "Agreement") in accordance with the following.

CLAUSES

1. Object

The object of the Agreement is to establish the terms and conditions which will be applied to the business relationship

whereby BELMAC will manufacture products as requested from time to time by ETHYPHARM.

2. Resources

The manufacture of the products will take place at BELMAC's laboratory located in Zaragoza and will be carried out by BELMAC personnel.

The equipment used in manufacturing the products will be provided by ETHYPHARM. ETHYPHARM FRANCE, as ultimate owner of the know-how employed in manufacturing the products authorises ETHYPHARM to use said know-how. ETHYPHARM, in turn, authorises BELMAC to use this know-how to manufacture the products under the terms and provisions of the Agreement.

For the purposes of the Agreement, the term "know-how" shall be deemed to include the industrial procedures and methods which are detailed in Annex 2 as well as the technology pertaining to the production guidebooks.

3. Term

The Agreement will come into effect on 1 April 1995 and will expire on 1 April 2000, unless previously rescinded by any party following that stated here below.

Any party may, after 1 April 1996, unilaterally terminate the Agreement by certified letter sent to the other party, provided that a notice of at least six-months in advance of the termination date is observed.

In the case that one party breaches any of its obligations as set out under the Agreement, the other party may unilaterally terminate the Agreement by certified letter, without prejudice to any other actions that the non-defaulting party may exercise and particularly to a claim for damages. In this case no advance notice shall be observed.

4. Manufacture of the products

The manufacture of the products shall be made with strict observance of the Spanish regulations in force, as well as of the know-how provided by ETHYPHARM.

The manufacture will be undertaken by BELMAC personnel and at BELMAC's premises, but supervised by ETHYPHARM and without prejudice to ETHYPHARM's faculties of inspection as set out in clause 11.

BELMAC, as a pharmaceutical laboratory will assume, vis-a-vis third parties, the liability derived from the manufacture of the products in the terms provided by the law. Notwithstanding that stated previously, BELMAC may claim that ETHYPHARM is liable in those cases in which the defect or error in the manufacture of the products stems from the equipment or know-how provided by ETHYPHARM.

5. Exclusivity

The obligations assumed by each party in the Agreement will be of an exclusive nature, so:

5.1 ETHYPHARM cannot request a different laboratory to manufacture the products (for itself or for clients) except in those cases wherein BELMAC cannot meet the terms and delivery dates requested by ETHYPHARM.

5.2 BELMAC cannot manufacture products with the know-how provided by ETHYPHARM for clients other than those provided by ETHYPHARM. However, the parties recognise that this exclusivity obligation:

- will not preclude BELMAC from manufacturing the products with technology other than ETHYPEARM's.
- will only be applied to the so-called "active sales" (those promoted by BELMAC), but not the so-called "passive sales" (those in which the client approaches BELMAC regarding the manufacture of the product without any prior sales effort on the part of BELMAC).

6. Procedure - Invoicing

6.1 Clients provided by ETHYPHARM and resident in Spain:

The procedure will be the following:

a) The client will send a letter to BELMAC, according to the sample attached in Annex 3, requesting from BELMAC the manufacture of certain products and acknowledging that such manufacture will be done with ETHYPHARM's know-how and that the products will be sold and invoiced to them by ETHYPHARM.

b) The client and BELMAC will formalise a "Contrato de Fabricación por Terceros" in respect to the specific product/s and for those cases deemed necessary in accordance with that provided in Royal Decree 1564/1992 of 18 December. The "Contrato de Fabricación por Terceros" will need to be authorised by the Spanish Ministry of